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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,598 | 03/08/2002 | Jose Cibelli | 60141.0068USU1 | 1067 |

23552 7590 08/11/2004

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

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| EXAMINER |
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BERTOGLIO, VALARIE E

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SA.

Office Action Summary**Application No.**

10/092,598

Applicant(s)

CIBELLI, JOSE

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

After further consideration, the previous Election/Restriction mailed 01/06/2004 has been vacated and replaced with the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7 and 25-27, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by knocking out a gene required for differentiation into a particular lineage, classified in class 800, subclass 24.
- II. Claim 8, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by recombinantly inserting a suicide gene operably linked to a specific promoter, classified in class 800, subclass 24.
- III. Claims 9-20,28-50,53 and 70-72, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by stably transfecting said cell with at least one oligonucleotide that encodes an RNA molecule that interferes with the expression of a gene, classified in class 800;536, subclass 24,24.5.

- IV. Claims 52,54,66-68, drawn to a tissue engineered from differentiated cells and methods of transplanting the tissue, classified in class 435, subclass 1.1.
- V. Claims 55-62, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by knocking out a gene required for differentiation into a particular lineage and correcting a harmful gene or adding a therapeutic gene, classified in class 800;424, subclass 24,93.1.
- VI. Claims 63-65, drawn to a method of therapy using cells that are derived from a genetically modified nuclear transfer embryo, classified in class 424, subclass 93.21.

Claims 1-6,21-24,51 and 69 link(s) inventions I-III. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6,21-24,51 and 69. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

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Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The methods of each of inventions I-III are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention I require knocking out a gene, using gene-targeting technology. The methods of Invention II require random transgene insertion technology. The methods of Invention III require RNAi or antisense RNA technology. No one method is required for the other. Each method results in a materially distinct embryo.

The methods of each of Inventions I-III and of Invention IV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Inventions I-III and Invention IV are patentably distinct because the methods of Inventions I-III can be used to generate a nuclear transfer embryo while the methods of Invention IV can be used to transplant tissue. The methods of Inventions I-III are not necessary for those of Invention IV. Inventions I-III are each classified differently from Invention IV. The burden required to search any of Inventions I-III and Invention IV together would be undue.

The methods of each of Inventions I-III and of Invention V are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially

distinct protocols and reagents. Inventions I-III and Invention V are patentably distinct because the methods of Inventions I-III can be used to generate a nuclear transfer embryo while the methods of Invention V can be used to make cells for use in gene therapy. The methods of Inventions I-III are not necessary for those of Invention V. Inventions I-III are each classified differently from Invention V. The burden required to search any of Inventions I-III and Invention V together would be undue.

Inventions I-III and Invention VI are patentably distinct because the methods of Inventions I-III can be used to generate a nuclear transfer embryo while the methods of Invention VI can be used to treat disease. The methods of Inventions I-III are not necessary for those of Invention VI. Inventions I-III are each classified differently from Invention VI. The burden required to search any of Inventions I-III and Invention VI together would be undue.

The methods of each of Inventions IV and V are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention IV involve transplant of a tissue. The methods of Invention V involve making a nuclear transfer embryo comprising a therapeutic genetic modification. The methods of Invention IV are not necessary for those of Invention V. Invention IV is classified differently from Invention V. The burden required to search Inventions VI and V together would be undue.

The methods of each of Inventions IV and VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

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The methods of Invention IV involve transplant of a tissue. The methods of Invention VI involve treatment of a disease state using cells. The methods of Invention IV are not necessary for those of Invention VI. Invention IV is classified differently from Invention VI. The burden required to search Inventions IV and VI together would be undue.

The methods of each of Inventions V and VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention V involve making a nuclear transfer embryo comprising a therapeutic genetic modification. The methods of Invention VI involve treatment of a disease state using cells that do not comprise a therapeutic genetic modification. The methods of Invention V are not necessary for those of Invention VI. Invention V is classified differently from Invention VI. The burden required to search Inventions V and VI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

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